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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/528,989	03/20/2000	Jean Marie Vogel	9676-292	6000

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WASHINGTON, DC 20001-2113

EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/528,989	Applicant(s) VOGEL ET AL.	
	Examiner Shengjun Wang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,7,8,11-20 and 52-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7,8,11-20 and 52-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of applicants' amendemnts and remarks submitted January 12, 2006 is acknowledged.

1. The terminal disclaimer filed on January 12, 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,790,456 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections 35 U.S.C. 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 55 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 55 recites "the polymer is not cross-linked." The limitation lack support from the application as original filed. It is noted the application specifically states "the microspheres of the present invention comprise *crosslinked polymers* that are high water absorbing and, thus, capable of swelling upon contacting with aqueous medium in certain conditions." See, page 12, lines 10-12 of the specification. The application provide no support for a microsphere comprising no-crosslinked polymer. Further, the application as whole, provide no written descriptions as to microsphere comprising non-crosslinked hydrophilic polymers that would meet the required

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properties, i.e., "swell to a predetermined size after injection." Note, non-crosslinked hydrophilic polymers are normally water soluble, not water swellable.

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4, 7-8, 11-20, 52-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The term "high" in claim 1 is a relative term which renders the claim indefinite. The term "high" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The claims are indefinite as to the water absorbing property. Note some of the polymers recited therein, such as polyacrylates, which read on polyacrylate salts and polyacrylate ester, may have distinct water absorbing property depending on the actual structure.

4. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required

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feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation acrylate polymers, and the claim also recites sodium acrylate polymers which is the narrower statement of the range/limitation.

Claim Rejections 35 U.S.C. 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 4, 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Boschetti et al. (US 5,635,215 IDS).

7. Boschetti et al. teaches the spherical particles herein and suspension composition comprising the same used for injection. The particles are made of polyacrylic polymer with about 10% of bifunctional monomer. The particle sizes are range from 10 um to 2000 um. specific range of particle size within the range of 10 µm to 2000 µm are disclosed. See, particularly, the examples 1-21. Note the intended use herein, i.e., “for tissue bulking” is not seen to further limit the composition. As to the limitation of “injectable through needles of about 18 to 26 gauge.” Note the particle disclosed by Boschetti et al. such as those with 300-400 µm would have reasonably expected to be injectable through such needles.

Claim Rejections 35 U.S.C. 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-4, 7, 8, 11-20 and 52, 54-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boschetti et al.

10. Boschetti et al. teaches the spherical particles herein and suspension composition comprising the same used for injection into tissue. The particles are made of hydrophilic acrylic co-polymer, and in preferred embodiment, with about 10% of bifunctional monomer. The particle sizes are range from 10 um to 2000 um. specific range of particle size within the range of 10 μ m to 2000 μ m are disclosed. See, particularly, the examples 1-21. The particles may be incorporated with other agents, such as dye, magnetic resonance imaging agent, or contrasting agent. The particles may also carry cell adhesion promoter. See, columns 3, lines 16-36, and the claims.

11. Boschetti et al. do not expressly disclose the composition would be injectable through needles of about 26 to 18 gauge, or the particular amount of the particles in the composition, or the other particular agents in the composition as recited herein.

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to adjust the particle size within the disclosed

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range so that the composition would be suitable for injection with any needle required in the method.

12. A person of ordinary skill in the art would have been motivated to adjust the particle size within the disclosed range so that the composition would be suitable for injection with any needle required in the method because it is disclosed that the composition should be injectable. Further, employment of suitable carrier for an injectable composition, such as saline solution, would have been obvious to one of ordinary skill in the art because saline is a well known biocompatible carrier. Further, the incorporation of other well-known therapeutical agents, such as anti-inflammatory agents, or cells, with the particle would have been obvious since the other agents are known to be useful as therapeutical agents. As to claims 54 and 55, note even though Boschetti et al. teaches particular example of crosslinked polymers, crosslinking is not required. See, particularly, claim 1. Therefore, the employment of non-crosslinked polymer would have been obvious.

13. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boschetti et al. for reasons discussed above, and further in view of Tahara et al. (U.S. 5,298,570).

14. Boschetti et al. does not teach expressly the employment of sodium acrylate vinyl alcohol copolymers as the hydrophilic acrylic polymer.

15. Tahara et al. teach sodium acrylate/vinyl alcohol copolymers are known hydrophilic biodegradable polymer. See, particularly, the example 6 in column 6 and the claims.

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16. Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use the sodium acrylate vinyl alcohol copolymers as the hydrophilic acrylic polymer.

A person of ordinary skill in the art would have been motivated to use the sodium acrylate vinyl alcohol copolymers as the hydrophilic acrylic polymer because hydrophilic acrylic polymers are generally known to be useful, and sodium acrylate vinyl alcohol copolymers is particularly known as hydrophilic polymer. The employment of the copolymer is seen to be a selection from amongst equally suitable material and as such obvious. Ex parte Winters 11 USPQ 2nd 1387 (at 1388).

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Response to the Arguments

Applicants amendments and remarks submitted January 12, 2006 have been fully considered, and are found persuasive with respect to the double patenting rejections and 112 first rejections set forth in the prior office action, but are not persuasive as to the rejections set forth above.

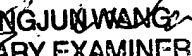
Applicants argue that Boschetti et al. reference does not disclose the microsphere is swellable, or comprising high water absorbing polymers. Note, any properties exhibited by or benefits provided the composition are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990. See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed product. Boschetti et al. teach generally a microsphere comprising a hydrophilic acrylic copolymer, particular examples disclosed including polyacrylamides (see the abstract, and the examples), polymers herein defined (see claims 1 herein). Therefore, there is substantial evidence support that the polymers employed by Boschetti et al. are essentially the same as herein claimed. It is applicants' burden to show that the polymers disclosed by Boschetti et al. is not "high" water absorbing, or the microsphere is not water swellable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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PRIMARY EXAMINER
Shengjun Wang
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Art Unit 1617